

- 16 -

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A method of treating premature ejaculation in a male comprising administering to the male an antidepressant via a route selected from the group consisting of:
  - i) mucosal administration;
  - 5 ii) administration to the lungs
  - iii) local administration to at least a part of the male genitalia and
  - iv) a combination of two or more of mucosal administration, administration to the lungs and local administration to at least a part of the male genitalia.
- 10 2. A method according to claim 1 wherein the antidepressant is administered prior to sexual activity
3. A method according to claim 1 or claim 2 wherein the antidepressant is administered during sexual activity
- 15 4. The method according to claim 1 wherein the mucosal administration is by nasal administration, buccal administration, rectal administration or combinations thereof.
5. The method according to claim 1 wherein administration to the lungs is by way 20 of inhalation.
6. The method according to claim 1 wherein local administration is directly to the penis.

- 17 -

7. A method according to any one of claims 1 to 3 wherein the antidepressant is administered by a combination of mucosal administration and local administration.

8. A method according to any one of claims 1 to 3 wherein the antidepressant is  
5 administered by a combination of mucosal administration and administration to the lungs.

9. The method according to any one of claims 1 to 3 wherein the antidepressant is administered by a combination of local administration and administration to the lungs.

10

10. The method according to claim 9 wherein local administration is topical administration to the penis and administration to the lungs is nasal administration.

15

11. The method according to any one of the preceding claims wherein the antidepressant is administered by a combination of mucosal administration, local administration and administration to the lungs.

12. The method according to any one of the preceding claims wherein the antidepressant is administered in an amount of between 0.1 and 1000 mg per dose.

20

13. The method according to any one of the preceding claims wherein the antidepressant is administered in an amount of between 1 and 100 mg per dose

25

14. The method according to any one of the preceding claims wherein the antidepressant is administered in an amount of between 5 and 25 mg per dose

15. The method according to claim 1 wherein a single antidepressant or single combination of antidepressants is administered by two or more routes selected from the mucosal administration, administration to the lungs and local administration to at least a 5 part of the male genitalia.

16. The method according to claim 1 wherein two or more different antidepressants or two or more different combinations of antidepressants are administered by two or more routes selected from the mucosal administration, administration to the lungs and local 10 administration to at least a part of the male genitalia.

17. The method according to claim 16 wherein the antidepressant combination includes serotonin reuptake inhibitor (SSRIs) and a monoamine oxidase inhibitor.

15 18. The method according to claim 1 wherein the antidepressant is massaged into the skin of the male genitalia prior to intercourse for about one minute.

19. The method according to claim 18 wherein the antidepressant is massaged into the skin of the male genitalia about 30 to 60 minutes prior to intercourse.

20

20. The method according to claim 1 wherein the antidepressant is taken nasally within 30 minutes prior to intercourse.

25 21. The method according to claim 20 wherein the antidepressant is taken nasally just prior to intercourse

22. The method according to claim 20 or 21 administered nasally by means of one or two metered doses shortly before intercourse.

5 23. The method according to claim 1 wherein the antidepressant is administered by way of a troche or suppository prior to intercourse.

24. A method of treating premature ejaculation in a male comprising the step of administering to the male an antidepressant, wherein the antidepressant is administered  
10 via a route selected from the group consisting of i) nasal administration, ii) administration to the lungs, iii) buccal administration, iv) administration to the penis, and v) a combination of two or more of nasal administration, administration to the lungs, buccal administration and local administration to the penis, thereby to provide a sufficient degree of anaesthesia to the penis to overcome premature ejaculation.

15

25. A method of prolonging sexual intercourse involving a male, the method including the step of administering to the male prior to intercourse an amount of an antidepressant effective to delay ejaculation; and wherein the antidepressant is administered via a route selected from the group consisting of: mucosal administration, administration to the  
20 lungs, topical administration to the male genitalia, and a combination of two or more of mucosal administration, administration to the lungs or topical administration to the male genitalia.

26. A method of prolonging sexual intercourse involving a male and a female, the  
25 method including the step of administering to the male prior to intercourse an amount of

- 20 -

an antidepressant effective to delay ejaculation without anaesthetising the female genitalia; and wherein the antidepressant is administered via a route selected from the group consisting of: mucosal administration, administration to the lungs, topical administration to the male genitalia, and a combination of two or more of mucosal  
5 administration, administration to the lungs or topical administration to the male genitalia.

27. A composition for the treatment of premature ejaculation, said composition comprising an antidepressant formulated for mucosal administration, administration to  
10 the lungs and/or local administration to at least part of the male genitalia.

28. The composition according to claim 27 wherein said antidepressant is selected from serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, monoamine oxidase inhibitors, norepinephrine dopamine reuptake inhibitors, serotonin  
15 antagonist and reuptake inhibitors, norepinephrine antagonist/serotonin antagonists, synthetically derived phenylpiperazine antidepressants, antagonists of central L2- $\alpha$ 2 auto and heteroadrenoceptors, and mixtures thereof.

29. The composition according to claim 28 wherein said antidepressant is a mixture of  
20 a serotonin reuptake inhibitor and a monoamine oxidase inhibitor.

30. The composition according to claim 29 wherein said serotonin norepinephrine reuptake inhibitor is a bicyclic, tricyclic or tetracyclic antidepressant.

31. The composition according to any one of claims 27 to 30 wherein said antidepressant is selected from paroxetine, fluoxoetine, sertraline, citalopram hydrobromide, fluvoxamine, sertraline, nortriptyline hydrochloride, clomipramine hydrochloride, dothiepin hydrochloride, Imipramine hydrochloride, mianserin hydrochloride, amitriptyline hydrochloride, phenelzine sulphate, tranylcypromine sulphate, isocarboxazid, moclobemide, serotonin and/or adrenalin update inhibitors such as venlafaxine, nefazodone hydrochloride, trazodone, bupropion, mirtazapine, doxepin hydrochloride, trimipramine or mixtures thereof.

10 32. The composition according to claim 31 wherein said antidepressant is selected from paroxetine, fluoxoetine, sertraline or mixtures thereof.

15 33. The composition according to claim 32 wherein said paroxetine is formulated as a hydrochloride or mesylate.

34. The composition according to any one of claims 27 to 33 including a carrier to facilitate the administration of the antidepressant.

20 35. The composition of any one of the preceding claims having a pH of around 7.4.

36. The composition according to any one of claims 27 to 35 formulated for local administration directly to the penis.

25 37. The composition according to any one of claims 27 to 36 for local administration to the penis in the form of a gel, lotion or a powder.

38. The composition according to claim 37 wherein said powder can be hydrated to form a gel or lotion.

5 39. The composition according to claim 38 wherein said gel is a hydrogel or an acrylic acid polymer.

40. The composition according to any one of claims 36 to 39 further comprising an enhancer agent for enhancing the absorption of the antidepressant agent through the  
10 skin.

41. The composition according to claim 40 wherein the enhancer agent is a cyclodextrin, water, a monohydric alcohol, a polyhydric alcohol

15 42 The composition according to claim 41 wherein the enhancer is ethanol, polyethylene glycol and propylene glycol or their mixtures thereof.

43. The composition according to claim 42 comprising:

about 20 to about 60% water;

20 about 80% to about 40% alcohols

1 to 10% Hydroxypropyl- $\beta$ -cyclodextrin (HPBCD) and wherein antidepressant agent and the HPBCD are typically present in the composition in a molar ratio of about 1:0.8 to 1:1.4 respectively.

- 23 -

44. The composition according to claim 43 wherein said HPBCD has a degree of substitution 5 to 7.

45. The composition according to any one of claims 27 to 44 wherein the 5 concentration of the antidepressant is between about 1 to 10% by weight of said composition.

46. The composition according to claim 45 wherein the amount is about 3 to 6% by weight of the composition.

10

47 The composition according to claim 27 for mucosal administration and formulated as a nasal spray, as a troche for buccal administration or in the form of a suppository for rectal administration.

15 48. The composition according to claim 47 wherein said nasal spray is in the form of an aqueous or non-aqueous gel, suspension, liposomal dispersion, emulsion or microemulsion or in powdered, microsphere, coated microsphere or liposomal form.

49. The composition according to claim 48 formulated for administration to the lungs 20 via inhalation and in the form of a dry powder, a micronized drug suspended in a liquefied propellant, or a drug dissolved, either alone or by way of a cosolvent, in a liquefied propellant.

50. The composition according to claim 49 wherein the particle size of the dry 25 powder is less than 10microns.

51. The composition according to claim 49 in the form of an aerosol and wherein said propellant is CFC (chlorofluorocarbon) or HFA (hydrofluoroalkane) propellants.

5 52. The composition according to claim 49 including a surface active agent selected from oleic acid, sorbitan trioleate, lecithin and their mixtures thereof.

53. A kit comprising an antidepressant formulated for nasal administration and an antidepressant formulated for local administration to at least part of the male genitalia.

10

54. A kit comprising an antidepressant formulated for administration to the lungs and an antidepressant formulated for local administration to at least part of the male genitalia.

15 55. A kit comprising an antidepressant formulated for nasal administration and an antidepressant formulated for administration to the lungs.

56. A kit comprising an antidepressant formulated for nasal administration, an antidepressant formulated for administration to the lungs and an antidepressant 20 formulated for local administration to at least part of the male genitalia.

57. A kit according to any one of claims 29 to 32 wherein said antidepressants are selected such that they act synergistically on administration.

- 25 -

58. Use of an antidepressant in the manufacture of a medicament for the treatment of premature ejaculation in a male, said antidepressant being administered via a route selected from the group consisting of i) mucosal administration, ii) administration to the lungs iii) local administration to at least a part of the male genitalia and iv) a 5 combination of two or more of mucosal administration, administration to the lungs and local administration to at least a part of the male genitalia.

59. Use of an antidepressant in the manufacture of a medicament for treating premature ejaculation in a male comprising the step of administering to said male an 10 antidepressant, wherein said antidepressant is administered via a route selected from the group consisting of i) nasal administration, ii) administration to the lungs, iii) buccal administration, iv) local administration to the penis, and v) a combination of two or more of nasal administration, administration to the lungs, buccal administration, and local 15 administration to the penis, thereby to provide a sufficient degree of anaesthesia to the penis to overcome premature ejaculation.

60. Use of an antidepressant in the manufacture of a medicament for prolonging sexual intercourse involving a male, said method including the step of administering to 20 said male prior to intercourse an amount of an antidepressant effective to delay ejaculation; and wherein said antidepressant is administered via a route selected from the group consisting of: mucosal administration, administration to the lungs, topical administration to the male genitalia, and a combination of two or more of mucosal administration, administration to the lungs or topical administration to the male genitalia.

- 26 -

61. Use of an antidepressant in the manufacture of a medicament for prolonging sexual intercourse involving a male and a female, said method including the step of administering to said male prior to intercourse an amount of an antidepressant effective to delay ejaculation without anaesthetising the female genitalia; and wherein said

5 antidepressant is administered via a route selected from the group consisting of: mucosal administration, administration to the lungs, topical administration to the male genitalia, and a combination of two or more of mucosal administration, administration to the lungs or topical administration to the male genitalia.